The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JUNZO SUNAMOTO, KUNIO SHIMADA, AKIO HAYASHI RYUZO HOSOTANI, YOSHIHIRO YANO and KAZUNARI AKIYOSHI

Appeal No. 2006-2554 Application No. 09/936,953

ON BRIEF

MAILED

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U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

Before SCHEINER, MILLS and LINCK, Administrative Patent Judges. LINCK, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection under 35 U.S.C. § 103(a) of claims 1, 4, 5 and 8-12, all of the pending claims in Application No. 09/936,953, filed Sept. 17, 2001 (hereafter the "'953 application").

Claim 1 is the only independent claim. It reads:

1. A cosmetic product comprising 99.999-50 wt. % of cosmetic components, a solvent containing at least one of a volatile oil and a volatile organic solvent and 0.001-50 wt. % of a pullulan-cholesterol derivative formed by substituting the hydroxyl groups of mono-saccharide units constituting the pullulan of the pullulan-cholesterol derivative, in

Application No. 09/936,953

a proportion of 0.01 to 20 groups per 100 monosaccharide units, by a radical represented by the formula (1):

$$-0 \stackrel{O}{\underset{H}{\stackrel{N}{\longrightarrow}}} \stackrel{R^1}{\underset{H}{\stackrel{O}{\longrightarrow}}} 0 \stackrel{R^2}{\longrightarrow} \dots (1)$$

in which R¹ denotes a hydrocarbon group containing 1-10 carbon atoms and R² represents a cholesteryl group.

The following references were cited and relied upon by the Examiner:

Sunamoto et al. ("Sunamoto") (English translation of JP 03-292301) Apr. 11, 1990 Ishiwatari et al. ("Ishiwatari") U.S. Pat. No. 6,074,652 Jan. 13, 2000

All of the pending claims stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sunamoto in view of Ishiwatari. Appellants describe the differences in scope between the pending claims. *See* Brief at 2-3. However, Appellants do not argue that these differences make the dependent claims separately patentable. Thus, we treat the dependent claims as standing or falling with claim 1.

We affirm.

BACKGROUND

The specification describes the problem of drying of skin "when the barriering function of keratin becomes decreased and the transcutaneous moisture transpiration becomes increased due to reduction of amount of skin secretory substances, in particular, sebum secretion, as well as due to decrease in the natural moisture-retaining factors, such as intercellular lipids and amino acids." Specification at 1. According to the specification, "a state in which the keratin moisture decreases below 10 % by weight is called dry skin." *Id.* at 2. In addition to the problems of dry skin, the specification

mentions similar problems with dry hair. *Id.* at 1-2. The object of the invention is to address problems with dry skin and hair. *Id.* at 4.

Prior art moisturizers are described, including ones incorporating a polyhydric alcohol, a polysaccharide, "such as hyaluronic acid, sorbitol or pullulan," or a "sphingolipid and ceramide which are constituents of the intercellular lipids in keratin." *Id.* at 2. These are not "sufficient in the moisture retaining ability," according to the specification, and may have an "unpleasant touch feel due to oily consistency . . . when a blocking agent is incorporated". *Id.* at 2-3. Finally, stability issues are noted. *Id.*

DISCUSSION

Concerning the application of § 103(a), the Supreme Court has articulated three factors that are relevant to an obviousness determination: (1) the scope and content of the prior art; (2) the differences between the prior art and claims at issue; and (3) the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

See also Answer at 3. Thus, *Graham* instructs us to consider these three factors prior to turning to the ultimate legal conclusion.

The Scope and Content of the Prior Art

The primary reference relied upon by the Examiner is Sunamoto. Sunamoto claims:

(1) A polysaccharide-sterol derivative prepared by substituting the hydroxyl groups of 0.1 to 6 units per 100 units of the saccharides constituting a polysaccharide with the groups represented by the following formula:

$$-0 \stackrel{O}{\underset{H}{\stackrel{}}} \stackrel{N}{\underset{H}{\stackrel{}}} \stackrel{O}{\underset{H}{\stackrel{}}} 0 \stackrel{R^2}{\underset{H}{\stackrel{}}} \cdots (1)$$

(wherein R^1 is a C_{1-10} hydrocarbon or a C_{1-10} hydrocarbon group substituted with an aromatic group, and R^2 is a sterol residue.) [Sunamoto at $2.^1$]

The polysaccharide can be pullulan and the sterol can be cholesterol. *Id.* at 5. In fact, "Working Example 4" discloses the preparation of an emulsion from 5 mg of a pullulan-cholesterol derivative, 10 mg oil (glycerol tricaprylate), and 1mL H₂O. *Id.* at 13-14. This example satisfies the limitation of claim 1, "99.999-50 wt. % of cosmetic components":

Exemplified [in Sunamoto] is an emulsion comprising 10 mg oil (glycerol tricaprylate, a cosmetic component), 5 mg pullulan-cholesterol derivative, and 1 mL water (a cosmetic component), a percent weight of 0.5% pullulan-cholesterol derivative and 95.5% cosmetic components (oil and water), see page 14. For the pullulan-cholesterol derivative having the structure of formula (1) of the instant claims, see page 2, claim 1. For 0.1-6 units per 100 monosaccharide untis, see page 2, claim 1." [Answer at 3.]

Sunamoto does not disclose "at least one of a volatile oil and a volatile organic solvent" (a limitation not present in any originally filed claim) or cosmetic uses.

The '953 specification defines the volatile oil as having "no special restriction" but gives "preference" to "hydrocarbon oils having a boiling point . . . from 60 to 160 deg C." Specification at 24. Named are light paraffin, several siloxanes and organic perfluorocompounds. *Id.* The specification does not appear to provide a description of "volatile organic solvent" but does state "the polysaccharide-sterol derivative is dissolved in a low-boiling cyclic silicone or in a hydrocarbon based low-boiling isoparaffin, both used as solvent for cosmetics". *Id.* at 20-21.

¹ Page numbers are to English translation of JP 03-292301.

² The Ishiwatari disclosure also clearly satisfies this very broad limitation. *See* Ishiwatari passim.

Disclosed uses for polysaccharide-cholesterol derivatives in Sunamoto are as coating materials for liposomes or emulsions and as carriers for pharmacological substances. Sunamoto at 3. Sunamoto further discloses that polysaccharide-cholesterol derivatives have been "utilized as polysaccharide coatings for liposomes . . . , as coatings for lipid emulsions . . . , and as polymeric surfactants used in the preparation process of polysaccharide coating emulsions." *Id.* The reference suggests that oil-in-water emulsions "exhibit . . . improved chemical and physical stabilities" when coated with polysaccharide-cholesterol derivatives "used for this purpose." *Id.*

The Examiner also relies upon Ishiwatari for its teachings of volatile oils and emulsified compositions used in cosmetic formulations. *See* Ishiwatari *passim*.

Ishiwatari's examples include volatile oils disclosed by appellants as appropriate for the presently claimed invention, e.g., dimethylpolysiloxane and octamethylcyclotetrasiloxane. *See*, e.g., col. 12, lines 30-31. The emulsified compositions also include water-soluble high polymers that can be natural high polymers, semisynthesized high polymers, and synthesized high polymers. Col. 10, lines 56-62. A "polysaccharide type" of natural high polymer is exemplified. Col. 10, line 63. Pullulan is one of the specific water-soluble natural high polymers expressly disclosed in Ishiwatari. Col. 30, line 21. According to Ishiwatari, water-soluble high polymers contribute long-term stability by "prevent[ing] the separation of emulsion particles." Col. 10, lines 56-59. Ishiwatari does not expressly disclose any polysaccharide-sterol polymers and therefore does not expressly disclose pullulan-cholesterol polymers such as those claimed in the '953 application.

The Level of Skill in the Art

The level of skill in the art is not challenged and is reflected in the references cited in the case.

The Differences Between the Prior Art and the Claims At Issue

We focus on claim 1 of the '953 application (the single independent claim).

While Sunamoto discloses substantially the same pullulan-cholesterol derivatives as those in claim 1, it does not disclose (1) "a solvent containing at least one of a volatile oil and a volatile organic solvent" or (2) use of the derivatives in cosmetics.

Sunamoto's primary focus appears to be on a process for making the polysaccharide-sterol derivatives such that the product is free of carboxyl groups which, according to the reference, "adversely affect[] the physical/chemical stabilities" and other advantageous characteristics of the derivatives. *See* Sunamoto at 4. Thus, the reference does not describe intended uses of the claimed derivatives in great detail. However, it does suggest that oil-in-water emulsions "exhibit . . . improved chemical and physical stabilities" when coated with polysaccharide-cholesterol derivatives "used for this purpose." *Id.* at 3.

Ishiwatari discloses a volatile solvent such as that claimed in the '953 application. Compare col. 12, lines 30-31 (octomethylcyclotetrasiloxane and dimethylpolysiloxane) with the '953 specification at 20. Further, the disclosed uses of the Ishiwatari emulsion are cosmetic uses. See Ishiwatari passim. Ishiwatari's objectives are "good usability" and "long-term stability and feeling of use." Col. 1, lines 43-47. However, Ishiwatari

³ Consistent with the specification, we interpret this phrase to require at least one volatile oil or one volatile solvent.

Application No. 09/936,953

does not expressly disclose inclusion of a polysaccharide-sterol derivative such as that claimed in the '953 application. *See id.*

The § 103(a) Determination In View Of These Graham Findings

All of the limitations of claim 1 are disclosed in the two cited references. Thus, the issue before us is whether one of ordinary skill in the relevant art would have been motivated to combine the teachings. According to the Examiner:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the pullulan-sterol compositions of Sunamoto et al. in the cosmetic water-in-oil emulsions of Ishiwatari et al. as pullulan-sterol compositions had previously been used in the formulation of emulsions (and liposomes) and that the pullulan-sterol emulsions exhibited improved chemical and physical stabilities. One would have been motivated to use the pullulan-sterol compounds in the Ishiwatari et al cosmetic emulsions in order to take advantage of the improved chemical and physical stability exhibited by the pullulan-sterol compounds [Final Office Action at 5-6].

We agree with the Examiner's determination that one skilled in the art would have been motivated to use Sunamoto's pullulan-cholesterol derivative, disclosed in Working Example 4, to make the claimed invention. Ishiwatari recognizes the value of high polymers, natural, semisynthesized and synthesized (including pullulan), to obtain long-term stability by preventing emulsion particle separation. See col. 10, lines 56-59. Sunamoto identifies pullulan-cholesterol derivatives as useful for this purpose. Sunamoto at 3 (oil-in-water emulsions "exhibit . . . improved chemical and physical stabilities" when coated with polysaccharide-cholesterol derivatives "used for this purpose"). Thus, one skilled in the art wishing to further stabilize the cosmetic emulsions of Ishiwatari would have been motivated to incorporate

Application No. 09/936,953

Sunamoto's pullulan-cholesterol derivative in place of or in addition to the high polymer disclosed in Ishiwatari.

Appellants argue that one of ordinary skill in the art would not have been motivated to make the claimed combination, i.e., "that there is no teaching contained within the four corners of the Sunamoto et al and Ishiwatari et al references which would motivate one of ordinary skill in the art to combine these references in the manner suggested by the Examiner." Brief at 5. We disagree, given the teachings described above.

Appellants further argue that Sunamoto's "target polysaccharide-steroid derivatives are used as coatings for liposomes or oil droplets" and therefore "would not be part of the composition disclosed in Ishiwatari". Reply at 2-3. According to Appellants, if Sunamoto's polysaccharide-sterol derivatives were used in place of Ishiwatari's polysaccharides, "they would destabilize the oil-in-water emulsified composition as opposed to stabilizing it." Reply at 2.

There is no evidence in the record to suggest that Sunamoto's derivatives and Ishiwatari's high polymers interact differently when used with the disclosed emulsions or to suggest the destabilization alleged by appellants. In fact, both Sunamoto and Ishiwatari prepare emulsions from mixtures that include the high polymer (pullulan-cholesterol in the case of Sunamoto). See Sunamoto's Working Example 4 (Sunamoto at 13-14) and those of Ishiwatari (col. 10, lines 56-col. 11, line 14). Further, Ishiwatari teaches that stability is achieved by preventing the emulsion particles from separating, suggesting a surface phenomenon similar to that suggested by the Sunamoto teachings. Finally, and more significantly, both references suggest the same purpose for adding a

high polymer—to provide stability to an emulsion. That suggestion is sufficient to motivate a skilled artisan to combine the teachings of Ishiwatari with those in Sunamoto, regardless of whether the stability is obtained through a surface phenomenon or through a different type of incorporation.

Finally, Appellants argue that the '953 specification examples establish "unexpectedly superior properties . . . sufficient to rebut any showing of prima facie obviousness." Reply at 3.

Initially we note that many of the examples do not appear to be according to the claimed invention which presently requires "at least one of a volatile oil and a volatile organic solvent." See claim 1. Only Examples 20-25 contain a volatile oil.⁴

Specification at 58-98. Considering these 5 examples (*id.* at 87-92), we conclude that they are not sufficient to overcome the Examiner's *prima facie* case of obviousness. First, it is impossible to tell whether the differences in the assessment values are statistically significant, given the lack of disclosure of any standard deviation. While appellants repeated their experiments a number of times, only average values are disclosed and not the values obtained for each experiment. *See, e.g., id.* at 88-89.

Second, to our knowledge, these tests are not standardized tests. Thus, there is no outside source to use to determine the validity or variability of the tests. Finally, the examples do not appear to be commensurate in scope with the claims. While "0.001-50 wt. % of a pullulan-cholesterol derivative" is claimed as part of the cosmetic formulation, the Examples 20-25 only test one concentration, i.e., 15 wt. % of the derivative. *See id.* at

⁴ Given the paucity of description of the "volatile organic solvent," it is difficult to determine whether any of the examples include such a solvent. We conclude that they do not.

87-91. See, e.g., In re Greenfield, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (test results for only one species "inadequate proof" to overcome prima facie case because not "commensurate in scope with the claims"), cited with approval in In re Peterson, 315 F.3d 1325, 1331, 65 USPQ2d 1379, 1383 (Fed. Cir. 2003).

We affirm the Examiner's rejection of all the pending claims as *prima facie* obvious over Sunamoto in view of Ishiwatari.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv) (2004).

AFFIRMED

TONI R. SCHEINER Administrative Patent Judge

DEMETRA J. MILLS Administrative Patent Judge

NANCY J. LINCK

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